INDEX NUMBER

JOURNAL OF VASCULAR SURGERY

VOLUME 18 NUMBER 6 DECEMBER 1993

OFFICIAL PUBLICATION
THE SOCIETY FOR VASCULAR SURGERY
INTERNATIONAL SOCIETY FOR CARDIOVASCULAR SURGERY
NORTH AMERICAN CHAPTER

ANNUAL JOINT MEETING
JUNE 5-8, 1994 SEATTLE, WASHINGTON

Mosby

ISSN 0741-5214

Transluminal placement of a prosthetic graft-stent device for treatment of subclavian artery aneurysm

James May, MS, FRACS, FACS, Geoffrey White, FRACS, Richard Waugh, MB, BS, DDR, FRACR, Weiyun Yu, MB, BS, and John Harris, MS, FRACS, FACS, *Sydney, Australia*

A 78-year-old man was seen with an expanding 5 cm false aneurysm of the right subclavian artery. This was treated by an intraluminal graft-stent device introduced through the brachial artery via a 16 F sheath. The graft was constructed from two polytetrafluoroethylene patches of 0.4 mm thickness and anchored in the subclavian artery by an 8 mm stainless steel stent. The procedure was monitored by an image intensifier. Completion arteriography and postoperative duplex scanning confirmed normal flow through the subclavian artery with no communication between the lumen and the aneurysmal sac. The patient recovered without complication. (J VASC SURG 1993;18:1056-9.)

The concept of a transluminally placed endovascular graft was initially proposed by Dotter.[1] Subsequently Balko et al.[2] reported the transfemoral placement of an intraluminal polyurethane-coated prosthesis in a sheep abdominal aortic aneurysm (AAA) model. Lawrence et al.[3] used a Gianturco stent (Cook, Inc., Bloomington, Ind.) wrapped in Dacron in dogs for the same purpose. The first investigator to use a balloon-expandable stent to anchor an intraluminal graft was Parodi.[4-6] The feasibility of treating experimental canine AAA by intraluminal grafts was also confirmed by Laborde et al.[7] The first report of the use of the technique in man was by Parodi et al.[8] They reported the treatment of five AAAs by transfemoral intraluminal Dacron grafts anchored by modified stainless steel stents. These aneurysms were all of the fusiform variety. A subsequent report by Parodi[9] included the treatment of a fusiform aneurysm of the common iliac artery by an intraluminal graft. We are unaware of any reports of a false aneurysm or an intrathoracic aneurysm being treated by this technique. We present here our experience with a false aneurysm of the subclavian artery treated by an intraluminal graft.

From the Department of Vascular Surgery, Royal Prince Alfred Hospital and Department of Surgery, University of Sydney.
Reprint requests: Professor James May, Department of Surgery, University of Sydney, NSW 2006 Australia.

0741-5214/93/$1.00 + .10 24/4/44848

CASE REPORT

A 78-year-old male patient required total parenteral nutrition because of pyloric obstruction. The initial attempt to gain vascular access for total parenteral nutrition was via the right subclavian vein. This was unsuccessful. A subsequent attempt to place a line in the left subclavian vein was successful. One week later it was noted that an expansile pulsation was present in the right supraclavicular fossa. A decision was made to keep the patient under observation rather than operate on the pulsatile swelling in the neck. During the following week the swelling was noted to have increased in size. At this point the patient was transferred to the Royal Prince Alfred Hospital. A duplex scan demonstrated a 5 cm false aneurysm in the right subclavian artery. An antegrade innominate arteriogram confirmed the finding of the duplex scan and demonstrated relatively normal subclavian and axillary arteries distal to the aneurysm (Fig. 1). Because the aneurysm was false and known to be increasing in size it was decided that it should be repaired. Because of its minimally invasive nature it was believed that an intraluminal graft was the procedure of choice.

Endovascular repair of aneurysms with materials currently used in vascular surgery is approved by the institutional review board, and informed consent was obtained from the patient. Laboratory and clinical experience in the use of intraluminal grafts for AAAs had previously been reported by the authors.[7,10]

The operation was performed with the use of general anesthesia on a radiolucent table. The patient was placed supine with the right arm outstretched on an arm rest at 90 degrees to the table. The neck and thorax were prepared and draped in addition to the arm in the event that the endovascular procedure was not possible.

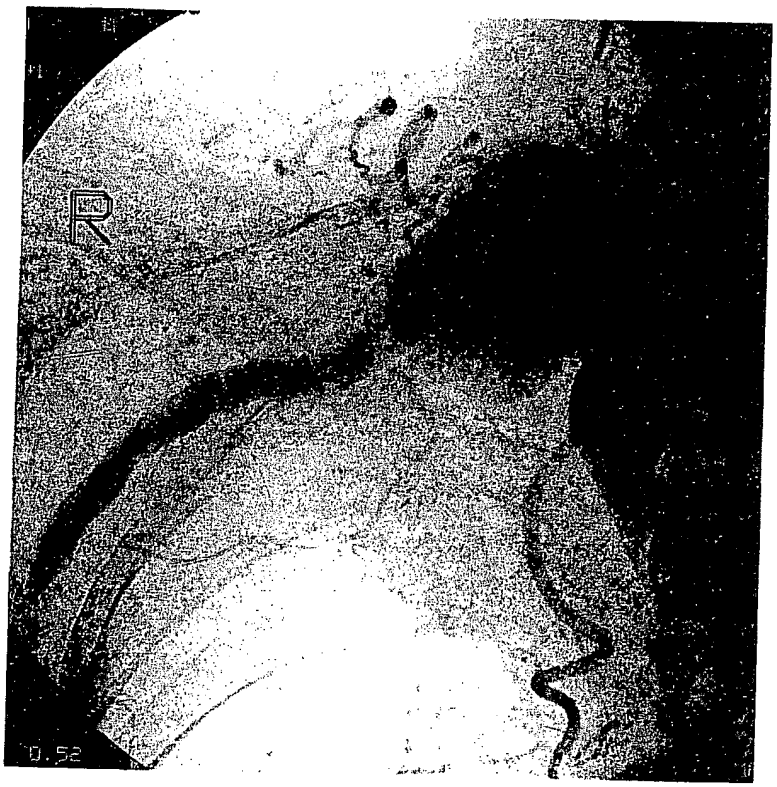

Fig. 1. Preoperative arteriogram showing false aneurysm of right subclavian artery. Note relatively normal subclavian and axillary arteries distal to aneurysm.

The graft was constructed from two polytetrafluoroethylene (PTFE) patches (Gore-Tex, W. L. Gore & Associates, Inc., Flagstaff, Ariz.) 0.4 mm in thickness, each measuring 6 × 2 cm. The patches were cut to 3.2 cm in length and sutured together along the long axis with 6-0 polypropylene sutures (Prolene; Ethicon Johnson & Johnson Medical, North Ryde, Australia). The flat graft was transformed into a cylinder 3.2 cm in circumference by suturing the two 4 cm sides together with 6-0 PTFE sutures (Gore-Tex, W. L. Gore & Associates). The circumference of 3.2 cm had been calculated to produce a tubular graft of 1 cm in diameter. This allowed for some overexpansion when the graft was positioned in the subclavian artery proximal and distal to the aneurysm. The diameter of the subclavian artery had been measured on the preoperative arteriogram (Fig. 1) at the points where it was first seen distinctly at the lateral margins of the aneurysm. The diameter was 0.83 cm for the proximal subclavian artery and 0.76 cm for the distal subclavian artery. A standard, 1 cm diameter, PTFE tube graft was not used because its thickness of 0.64 mm would have added to the bulk of the graft-stent device.

The completed graft was furled around an unexpanded 8 mm Palmaz stainless steel stent (Johnson and Johnson Interventional Systems, Warren, N.J.) mounted on a balloon catheter (Fig. 2). The graft was secured to the stent and prevented from unrolling by two 6-0 plain catgut circumferential ties, placed 0.2 cm and 2.2 cm from the proximal end of the graft.

The right brachial artery was exposed in the upper arm. A guide wire was introduced into the brachial artery and passed without difficulty through the subclavian artery, past the aneurysm. An on-table arteriogram demonstrated the position of the aneurysm. With the angiogram used as a guide, a skin clip was placed at the neck of the aneurysm as a radiopaque marker to facilitate further manipulation.

A 16 F peel-away sheath and dilator (William A. Cook [Aust], Queensland, Australia) was introduced into the brachial artery over the guide wire through a longitudinal arteriotomy. The sheath was selected because of its size, compliance, and flexibility rather than its peel-away characteristic. The sheath was advanced into the subclavian artery to a point just distal to the aneurysm. The graft-stent device was delivered to the predetermined site of the aneurysm by advancing the balloon catheter over the guide wire. The stent was deployed, thus anchoring the graft within the normal subclavian artery proximal to the aneurysm. Despite extensive preoperative laboratory testing, difficulty was experienced in expanding the stent. The original balloon on which the stent was mounted plus a replacement balloon both ruptured with the stent partially expanded. A Blue Max (Meditech/Boston Scientific, Waterton, Mass.) 8 mm balloon was finally introduced and accomplished complete expansion of the stent. During these balloon cath-

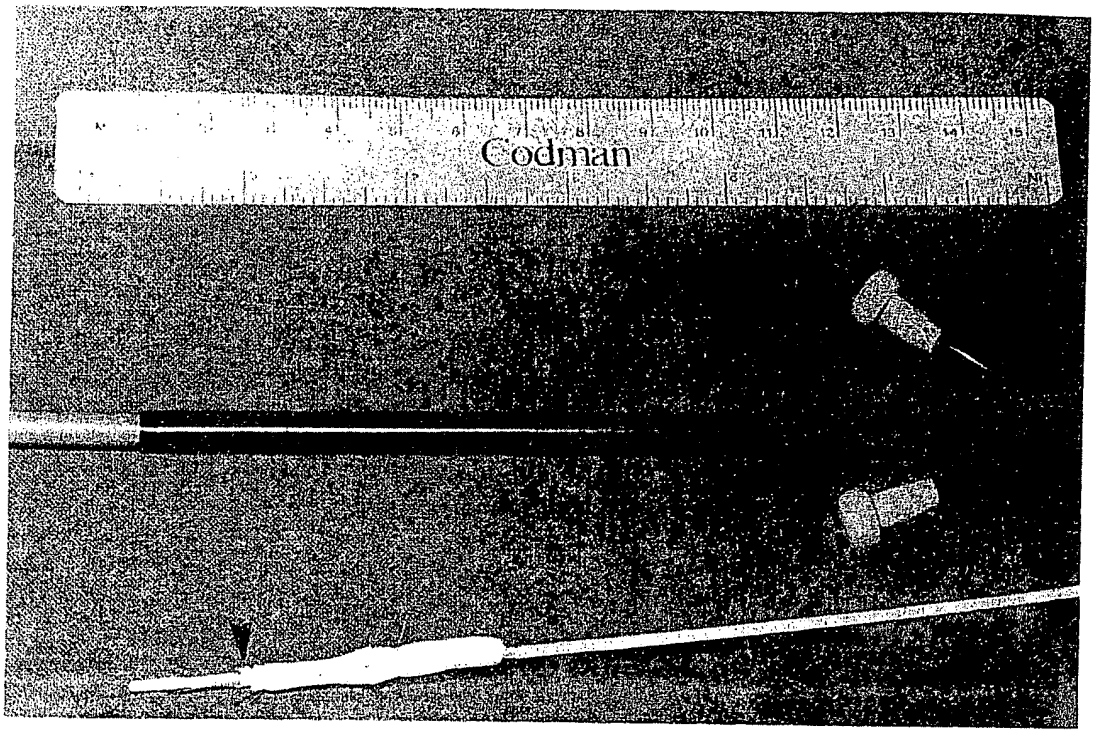

Fig. 2. Graft-stent device is shown mounted on balloon catheter in *lower half* of figure. Proximal one quarter of stent can be seen projecting beyond graft *(arrow)*. Remainder of stent is covered by furled graft. 16 F sheath and dilator are shown *above*.

eter exchanges, the introducing sheath was advanced to abut and stabilize the graft in its correct position.

After deployment of the stent a completion arteriogram demonstrated normal flow through the subclavian artery without leakage of contrast into the aneurysmal sac (Fig. 3). The arteriogram also demonstrated unobstructed flow up the vertebral and common carotid arteries, which confirmed that the graft-stent had not been positioned at too proximal a site in the subclavian artery.

The patient made an uncomplicated recovery and was allowed to return home after 4 days in the hospital. A duplex scan before discharge confirmed normal flow through the subclavian artery with complete exclusion of the aneurysmal sac, which was shown to be thrombosed. Noninvasive vascular laboratory studies confirmed normal blood flow to the right arm. The patient has been followed up for 4 months, and the circulation to the right arm remains normal.

DISCUSSION

The treatment options for this patient were conservative observation, open operation, or endovascular repair. Conservative management involved considerable risk in view of the size of the aneurysm, its observed increase in size, and the geographic isolation of the patient from a specialized vascular service. Open operation on the subclavian artery may be approached through a supraclavicular incision or by thoracotomy. In this case, control of the proximal subclavian artery could be obtained safely only by thoracotomy. Attempted control of the subclavian artery by the supraclavicular approach would have necessitated going into the lumen of the false aneurysm because the sac of the aneurysm presented above the clavicle. Proximal control of the aneurysm by temporary inflation of a balloon in the first part of the subclavian artery was contemplated as an adjunct to a supraclavicular surgical approach to the aneurysm. There was concern, however, about the risk of embolization up the vertebral artery as a result of manipulation at its origin. It seemed, therefore, that endovascular repair of the aneurysm was the best option in this case.

Endovascular repair of the subclavian artery was reported by Becker et al.[11] They had inadvertently entered the subclavian artery while attempting to cannulate the subclavian vein. They chose to leave the cannula in situ until they had introduced an intraluminal covered stent into the subclavian artery via the axillary artery. This was deployed at the site of the injury after withdrawal of the errant subclavian line. Although the approach was similar, their report was concerned with repair of a traumatized artery and

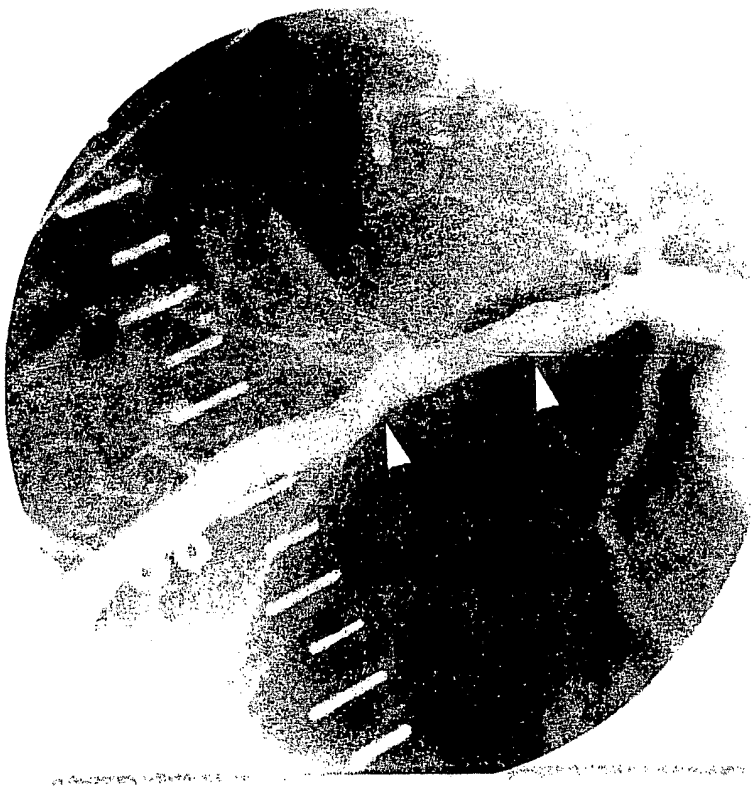

Fig. 3. Completion arteriogram showing normal flow through subclavian artery without leakage of contrast into aneurysm sac. Proximal and distal ends of graft-stent device are indicated by *arrows*. Heavy metallic markings of radiopaque ruler are also seen.

prevention of hemorrhage, rather than repair of a proven aneurysm.

This case demonstrates that endovascular repair of a subclavian false aneurysm is feasible and safe. Thoracotomy and intensive care nursing were avoided. The technique warrants further trial and clinical evaluation.

REFERENCES

1. Dotter CT. Transluminally placed coil spring endarterial tube grafts: long term patency in canine popliteal artery. Invest Radiol 1969;4:329-32.
2. Balko A, Piasecki GJ, Shar DM, Carney WI, Hopkins RW, Jackson BT. Transfemoral placement of intraluminal polyurethane prosthesis for abdominal aortic aneurysm. J Surg Res 1986;40:305-9.
3. Lawrence DD, Charnsaugavej C, Wright KC, Gianturco C, Wallace S. Percutaneous endovascular graft: experimental evaluation. Radiology 1987;163:357-60.
4. Parodi JC, Palmaz JC, Barone HD, et al. Tratamiento endoluminal de los aneurismas de aorta abdominal: estudio experimental. In: Capdevila JM, ed. Proceedings of II Convencion de Cirujanos Vasculares de Habla Hispana. Buenos Aires, Argentina, 1990:122.
5. Palmaz JC, Parodi JC, Barone HD, et al. Transluminal bypass of experimental abdominal aortic aneurysm. Presented at the seventy-sixth Scientific Assembly and Annual Meeting of RSNA, 1990.
6. Parodi JC, Palmaz JC, Barone HD, et al. Transluminal aneurysm bypass: experimental observations and preliminary clinical experiences. Presented at International Congress IV. Endovascular Therapies in Vascular Disease, 1991.
7. Laborde JC, Parodi JC, Clem MF, et al. Intraluminal bypass of abdominal aortic aneurysm: feasibility study. Radiology 1992;184:185-90.
8. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:491-9.
9. Parodi JC. Unpublished data presented at the Joint Annual Meeting of the Society for Vascular Surgery and International Society for Cardiovascular Surgery, Chicago, Illinois, 1992.
10. May J. Unpublished data presented at the Joint Annual Meeting of the Society for Vascular Surgery and International Society for Cardiovascular Surgery, Chicago, Illinois, 1992.
11. Becker GJ, Benenati JF, Zemel G, et al. Percutaneous placement of a balloon-expandable intraluminal graft for life threatening subclavian arterial hemorrhage. J Vasc Interv Radiol 1991;2:225-9.

Submitted Oct. 12, 1992; accepted Dec. 10, 1992.